

REMARKS

Reconsideration of amended claims 1, 3 and 5-7 is respectfully requested. Claims 2 and 4 are canceled by this Amendment. Also, claims 8-17 are canceled as they are directed to a non-elected invention. Claims 1, 3, 5 and 7 are amended.

The amended claims are directed to a container to hold contact lens disinfecting solution that comprises poly(hexamethylene biguanide) (PHMB) within a recited concentration range, and one or more surfactants which includes a poloxamer or poloxamine surfactant.. The claims are supported in-part by test solution 2 on page 14, the data of Tables 2 and 4, and paragraphs [0016-17] and [0027]of the application.

To begin, Applicants submit that contact lens disinfecting solutions containing the recited concentration range of PHMB and the recited surfactants were known at the time of this application's filing date. In fact, Bausch & Lomb under the Tradename ReNu®, and other manufacturers of contact lens care solutions, have sold such lens care solutions prior to Applicant's date of invention. Applicants also submit however, that these solutions were and continue to be packaged in white, high density polyethylene (HDPE) bottle enclosure or container.

The rejection of claims 1, 3, 4 and 6 under 35 USC 103(a) as obvious over Asgharian (US 6228323) is respectfully traversed with respect to the amended claims and the submission of additional experimental data in tabulated form below that demonstrates the advantages of packaging a contact lens disinfecting solution that comprises the recited range of PHMB and one or more of the recited surfactants in a PET bottle compared to packaging the same solution in a HDPE bottle. In response to the examiner's statement that the data included in the application is insufficient to overcome the *prima facie* case of obviousness, applicant's attorney obtained additional experimental data from one of the inventors. This additional data was available at the time of filing, but was unfortunately not included in the application.

For easy reference, Tables 1, 4 and 8 include the raw and mean initial time data for test solution 1 in PET and HDPE. Applicants recommend that the mean initial data in each of these three Tables be used to compare with the mean biocidal data reported in Tables 10 and 11 for

each of PET and HDPE. In particular, Applicants direct the examiner's attention to the biocidal data related to *Fusarium solani* (Fs), which is included in Tables 10 and 11 for reference.

As indicated by the biocidal stability data, test solution 1 remains biocidal active in the PET container but not in the HDPE container. At three months, there is statistically no change in the biocidal efficacy of test solution 1 in the PET container. In contrast, there is greater than a 50% reduction in biocidal activity of test solution 1 in HDPE. Similar results are indicated with the biocidal stability data at six months for test solution 1 in PET and HDPE containers. There is about a loss of 30% activity of the solution in the PET container at six months. In contrast, test solution 1 is virtually inactive, that is, shows no statistical biocidal activity in the HDPE container at six months. Given this test data Applicants respectfully submit the examiner's *prima facie* case of obviousness has been rebutted, and request that the rejection be withdrawn.

A similar argument can be made with respect to the other pending rejections of claims 1, 3 and 5-7 stated in the Official Action. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Table 1. Log Reduction of PHMB Formulation in PET; Initial Time

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
1	1	3.6	4.5	2.5	2.6	1.8
	4	4.0	4.5	4.6	3.5	3.0
2	1	4.4	4.6	3.9	2.5	2.3
	4	4.9	4.6	4.7	3.9	3.8
mean	1	4.0	4.5	3.2	2.5	2.0
	4	4.4	4.5	4.6	3.7	3.4

Table 2. Log Reduction of PHMB Formulation in PET; 3 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
1	1	4.6	3.7	1.2	3.0	1.9
	4	4.9	4.9	3.2	4.0	3.1
2	1	2.7	2.8	3.1	3.0	2.3
	4	4.6	4.6	4.6	3.6	3.2
mean	1	3.6	3.2	3.5	3.0	2.1
	4	4.7	4.7	3.9	3.8	3.1

Table 3. Log Reduction of PHMB Formulation in PET; 6 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
1	1	4.7	3.9	2.2	2.8	1.8
	4	4.7	4.7	4.6	3.4	2.8
2	1	4.7	2.8	1.8	2.9	0.8
	4	4.8	4.9	4.5	3.1	1.7
mean	1	4.7	3.3	2.0	2.8	2.3
	4	4.7	4.8	4.5	3.2	2.2

Table 4. Log Reduction of PHMB Formulation in PET; Initial Time

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
3	1	4.6	3.4	2.6	2.9	3.7
	4	4.6	4.7	4.6	3.7	4.2
4	1	3.4	4.2	3.0	3.0	2.8
	4	4.8	4.6	4.6	3.8	3.9
5	1	4.8	2.4	2.8	1.5	1.7
	4	4.9	4.1	3.0	3.0	2.7
mean	1	4.3	3.3	2.8	2.5	2.7
	4	4.8	4.5	4.1	3.5	3.6

Table 5. Log Reduction of PHMB Formulation in PET; 3 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
3	1	4.8	4.6	4.6	3.4	2.7
	4	4.8	4.6	4.6	4.4	3.9
4	1	2.5	4.7	4.0	2.9	1.9
	4	3.4	4.7	4.8	3.9	3.4
5	1	2.3	4.1	2.0	2.8	2.7
	4	3.6	4.7	4.7	4.3	3.7
mean	1	3.2	4.5	3.5	3.0	2.4
	4	3.9	4.7	4.7	4.2	3.7

Table 6. Log Reduction of PHMB Formulation in PET; 6 months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
3	1	3.9	2.8	3.1	3.1	---
	4	4.9	4.8	4.6	3.6	2.6
4	1	3.2	4.4	3.3	2.9	1.0
	4	4.7	4.8	4.7	3.8	2.1
5	1	3.5	4.8	3.7	3.0	1.3
	4	4.9	4.8	4.7	4.2	2.8
mean	1	3.5	4.0	3.4	3.0	1.2
	4	4.8	4.8	4.7	3.9	2.5

Table 7. Log Reduction of PHMB Formulation in HDPE; Initial Time

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
6	1	3.5	2.4	2.2	2.3	1.2
	4	4.8	4.5	4.0	3.6	2.4
7	1	4.5	2.3	2.6	2.4	1.4
	4	4.8	4.0	4.6	3.0	2.2
8	1	3.1	2.5	2.0	2.6	1.9
	4	4.7	4.7	3.4	3.2	3.0
mean	1	3.7	2.4	2.3	2.4	1.5
	4	4.8	4.4	4.0	3.6	3.9

Table 8. Log Reduction of PHMB Formulation in HDPE; 3 Months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
6	1	1.9	2.0	1.9	2.4	0.9
	4	4.3	3.4	4.0	3.1	2.0
7	1	3.4	2.3	3.2	2.6	0.8
	4	4.7	3.2	4.5	3.0	1.2
8	1	2.9	2.4	2.2	2.5	0.7
	4	4.6	3.1	4.0	3.1	1.3
mean	1	2.7	2.2	2.4	2.5	0.8
	4	4.5	3.2	4.2	3.1	1.5

Table 9. Log Reduction of PHMB Formulation in HDPE; 6 months, 40 °C

Trial No.	t (hr)	Sa	Pa	Sm	Ca	Fs
6	1	1.7	2.7	2.8	1.6	0.4
	4	3.1	4.5	4.1	2.2	0.5
7	1	2.0	2.4	3.3	2.1	0.5
	4	2.9	4.7	4.7	3.2	1.1
8	1	0.9	3.3	1.4	0.9	0.1
	4	1.4	4.6	3.3	1.4	0.3
mean	1	1.5	2.8	2.5	1.5	0.3
	4	2.5	4.6	4.7	2.3	0.6

**Table 10. Summary of Mean Log Reduction of PHMB Formulation.
3 months, 40 °C**

mean trial nos.	t (hr)	Sa	Pa	Sm	Ca	Fs	Fs t ₀
1/2 PET	1	3.6	3.2	3.5	3.0	2.1	2.0
	4	4.7	4.7	3.9	3.8	3.1	3.4
3/4/5 PET	1	3.2	4.5	3.5	3.0	2.4	2.7
	4	3.9	4.7	4.7	4.2	3.7	3.6
6/7/8 HDPE	1	2.7	2.2	2.4	2.5	0.8	1.5
	4	4.5	3.2	4.2	3.1	1.5	3.9


**Table 11. Summary of Mean Log Reduction of PHMB Formulation.
6 months, 40 °C**

mean trial nos.	t (hr)	Sa	Pa	Sm	Ca	Fs	Fs t ₀
1/2 PET	1	4.7	3.3	2.0	2.8	2.3	2.0
	4	4.7	4.8	4.5	3.2	2.2	3.4
3/4/5 PET	1	3.5	4.0	3.4	3.0	1.2	2.7
	4	4.8	4.8	4.7	3.9	2.5	3.6
6/7/8 HDPE	1	1.5	2.8	2.5	1.5	0.3	1.5
	4	2.5	4.6	4.7	2.3	0.6	3.9

Applicants assert that the present is in condition for allowance. An early and favorable action on the merits is solicited.

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